

CLFM

2/12/03

Discussed need to manage Plus as Plus is not putting in 40 hrs/wk & is not managing his direct reports.

Discussed frustration of raw materials group as they do not see any methods coming out of AS+T (based on conversation between myself & Susan Bossi on 2/11/03).

Told Clem that he gave the perception of not being available or aware of the daily ongoing of his group. I suggested he keep his door open (it's usually closed) & be more active in the daily operations of his group.

I also requested the raw material vl. doc & some examples of reports/protocols from Plus group.

I also explained that he needed to be fully aware of Barbara's workload, state of the QSE II, etc.

2/13/03

Clem gave me 2 ex. of validation protocol. I asked for an ex. of a repeat but he said none have been completed yet. The group has existed for > 1 yr.

WYETH00454

Clem

8/13/03

I've been asking Clem to put together a timeline (ie list of activities) for lab certification. He resisted for over a month & at our staff meeting, I told him I needed a written, well thought out list as Pei wanted it. He replied, "I didn't know Pei wanted it."

He had come with some hand written notes.

Previously I had asked for cert. protocol & MOP. I asked him not to delegate it. However, Pei took the initiative to do it & submit it to QRM. Clem was not aware that Pei had done this.

When I questioned him, he said it was ok, as he was working on the same thing. I explained that the duplication of effort was not efficient.

He was also not aware of the status of the lyophil lab notebook SOP (approved in revision). He was supposed to follow up on this from our 8/5/03 1-1 mtg.

WYETH00455

1/07

Sue Monihan (St. Louis) called me to ask for clarification of Clem's role in the tech transfer of assays from St. Louis to Andover.

I explained that Clem's role was to be the major leader for this tech transfer.

Sue expressed her concern that Clem was looking at the big picture only & was not interested in the details. She said Clem showed "no sense of urgency". When she asked Clem specific questions such as "was the equipment transferred to Development" or what about "SOPs" & "training"? Clem responded, "oh oh no, it's fine".

Sue was also concerned that Clem planned & spent the day in St. Louis at Tiny Bicks & that he should have been talking to a number of other individuals.

I tell Sue I will follow up & thanked her for the feedback.

WYETH00456

Documentation

DM
3 June 2004

January 22, 2004

I had a meeting with Clem and explained that there was concern regarding his success in leading the efforts towards transferring the Refacto QC technology from St. Louis to Andover. I explained that to date we weren't being updated as to accomplishments. Clem responded that individuals that had information were not coming forward with it. I asked him if he asked them for information and he replied that he shouldn't have to. I disagreed and told Clem everyone was very busy and he was assigned to the project full time and that he would be held accountable. If he needed information, it was his responsibility to ask for it. I also gave him the feedback that he seemed disorganized and that disorganization invites others to believe that the work is not progressing.

Clem also explained that there was lots going on and that he was very busy and didn't really have time to organize things. I told Clem that without the organization we could not be certain as to whether we were catching things before they fell through the cracks. Clem said he didn't have enough time and I told him I didn't see 8 hours/day of work being completed. Clem said, "Let's not go through that again". I did not directly respond to his comment but did tell him that coming in at 9:30 and leaving by 5:30 was inappropriate considering the nature of the project and his position in the company. He said sometimes he is here until 6 or 7.

Clem also insisted that he called the meeting last week to give the update but that Sharleen took over. I explained that part of the problem was that he spent the first half of the meeting reading some cryptic notes to us and that as action items were being identified Clem was not writing them down so Sharleen assumed the role by writing things on the whiteboard and assigning individuals. I also explained that we had asked for a status update meeting and that Clem wanted a "working meeting". I told him a "working meeting" was fine but it was inappropriate for Sharleen and I to spend the time there as we didn't have the information and we just wanted to be updated. I also pointed out that if an agenda had been prepared, things might not have progressed in that meeting as they had.

Finally, I went over a written document of expectations that I assembled for Clem. The due date is Wed, Jan 28th, 2004 (although verbally I said Wed or Thurs). I went into detail as to why assembling the data in an easy to read spreadsheet would help the situation. I handed the document to Clem and he agreed to work towards meeting the expectations.

January 23, 2004

Clem arrived at about 9:15 this morning. I asked Clem to put together a brief status update (in an email) for myself, Sharlene and David. Clem resisted and reminded me that doing that would take time away from the project. I told Clem that was always the case (for all of us in all projects) and that I wasn't asking for details but an overview, only. I even gave him some examples for sentences. I told him he shouldn't spend more than 20 or 30 minutes on it.

At about 3:30, Clem called me (from his office) and said he would rather not do the update, as he was busy putting the tables together, (i.e., organizing the information). I told him that it was important that he communicates the status of the transfer but he resisted again. I then suggested that he send an email and acknowledge that he is assembling the data for next week. Clem sent this email out at about 4:00. At 4:05, he stopped by my office to tell me he was leaving early as he was traveling to NJ for the weekend.

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January 30, 2004

I asked Clem to update me on the St. Louis Refacto project. We met at about 2:00. Clem told me everything "was going nicely" and that all issues with raw materials and assays were now under control. I asked if he was going to distribute a cleaned up version of his assay/dept. responsibility table and he said he would. I then suggested that he have a videoconference call between key players in Andover and St. Louis. Clem seemed reluctant and unclear as to the objective, so I explained that we needed to be sure nothing fell through the cracks and everyone was on the same page. Clem agreed to have the meeting set up. On Friday afternoon we received an invitation to a meeting between St. Louis and Andover for Monday (Feb. 2nd at 1:00).

Feb. 2, 2004

Sharleen called me this morning and asked if Clem had an agenda. I told her I wasn't aware of one. Sharleen pointed out that it wasn't clear if the correct individuals were invited and that without an agenda it was difficult to make that decision. I agreed but wasn't able to connect with Clem prior to the meeting. At the meeting we discussed a number of items that would have fallen through the cracks if we hadn't had the conference meeting. At one point Clem made the recommendation that the one stage clotting assay should be transferred directly from Andover Development to Biovitrum as there was no need to transfer it to QC first. There was strong disagreement on this issue at the time as both David Holmes and Sue Monihan pointed out that such an arrangement was

WYETH00469

unacceptable and the method would have to go through AS&T first. It was clear that Clem was making recommendations and assumptions without getting the necessary input first. In fact, he had mentioned this to me on Friday and I told him I wasn't sure that was ok to do and he assured me it was no problem. During the meeting it was also stated (by Clem) that controls, standards, columns, etc. were coming back to Andover. When I asked whom would they be shipped to, Clem replied "to me, care of Isabelle". I then asked for clarification as I thought Sample Management should get standards and controls. The rest of the group agreed and it was clear to me that Clem was making assumptions and decisions and was not speaking to the necessary individuals before making these decisions. The issue that the chromogenic standard, S8-14, would need qualification by Andover also came to light. This detail would also have been lost if we hadn't had the meeting. Towards the end of the meeting, Clem was ending the meeting and said, well "thanks for participating" and began to hang up. I interjected that we should review action items. Clem said, "Well, I can just read off what I wrote". He went through the list and everything was captured. However, the overall impression was that Clem had little interest and/or skill in running the meeting.

After the conference call ended, the Andover group continued discussions for a brief period. The issue of BA conducting the assays was discussed and it was determined that Clem had not followed up with BA as to how long they would support the effort. He volunteered to do so and said, "Should I just ask them how long they'll do this". I responded by giving an example of how I would approach it but it was clear that Clem didn't have the skills for these negotiations.

February 3, 2004

I followed up with Sharleen this morning and asked her how she felt the meeting went in terms of Clem's leadership/management skills. Sharleen again stated that it was inappropriate to set the meeting up and not to have an agenda. Without giving any explanation, Clem looked to St. Louis to begin the meeting but without knowing the purpose of the meeting, there was some hesitation on their end. In summary, Sharleen thought that Clem was unprepared for the meeting. However, she did note that Clem did take notes and had captured all the action items.

February 12, 2004

Clem left for half the day (sick).

WYETH00470

February 13, 2004

Clem called in sick.

February 18, 2004

Clem called in sick.

February 19, 2004

I met briefly with Clem and told Clem that I was concerned and surprised that he had made the decision to move Refacto stability testing from BA to AS&T without consulting myself or the other supervisors. This decision resulted a number of individuals being pulled off of IL-11 projects to spend a considerable amount of time doing Refacto stability testing. This decision was brought to my attention by one of the analysts in the group and confirmed during a conversation I had with Sharleen Mile (who had heard it from one of her staff). Clem's response to this was difficult to follow as he spoke in vague generalities. I told him I wanted him to set up a meeting with myself, Dan, Louise and Isabelle so that we could figure out how and why this decision was made. I also asked him to put together a list of what assays were in BA prior to the closing of the St. Louis plant.

Subsequent to this meeting, Clem set the meeting up for February 24th. However, due to the Internal QA audit of AS&T, I asked Clem to reschedule it, which he did.

February 25, 2004

During our weekly update meeting, I asked Clem what he had been involved in doing. He stated that he was working on a plan to transfer the assay and that he was putting time line together. However, I could not discern any particular tasks that Clem had undertaken over the last week or so. I asked Clem if he had enough to do and he said "yeah".

February 26, 2004

I met with Clem, Isabelle, Dan and Louise regarding the Refacto stability program. Clem wanted to discuss plans moving forward to transfer the assay to DP but I wanted to focus on how we got to where we are. Clem had not prepared a list of assays that belonged to BA prior to the St. Louis closing. Instead, I got up to the board and with the help of the group was able to get a relatively accurate list of assays. When I questioned Clem's reasoning behind

making the decision that AS&T should do so many of these assays, his response was inarticulate and unclear. At one point he said that it would be easier to transfer these assays if we were doing them ourselves. I asked if he consulted with anyone else in AS&T before making these decisions and he said "no". He then said we should talk about the plans for transferring these assays. He made a timeline beginning in April. I asked if he spoke with anyone from the receiving labs regarding this timeline and he said "no". I told him I had received feedback that the testing labs couldn't take these assays until August and that before he made a timeline he needed to talk to the involved parties. Clem responded that it was a timeline and the start date could be moved as needed. I pointed out that although that was typical of timelines it didn't necessarily help us with the current situation. Clem said I needed to talk to Sharleen to get commitment first. I suggested he talk to Sharleen but Clem declined and said I needed to talk to her and then he could get involved afterwards. I pointedly asked him "So, I need to take care of this?" Clem said "yes".

Sometime during the middle of the meeting, I was thinking out loud as to how AS&T could complete these assays for stability. I remarked that we had 30 days to initiate testing (as Clem had told me this in a previous meeting in my office). Isabelle corrected me and said that we had 30 days to complete the testing. Clem seemed surprised and asked Isabelle who told her that. Isabelle replied "Tina Laramie". Clem said, "she's telling different people different things."

Immediately prior to the end of the meeting, Clem asked if he should concentrate on a timeline for transferring these assays. I said Clem should start working on AQ401 ("needs assessment") for transferring several of these assays. In addition, I asked him to open a dialogue with the development group to negotiate a compromise in terms of returning some of these assays to BA. Clem agreed.

February 26, 2004

I spoke briefly with Monica Snow deal regarding Tina Laramie's role in stability. During the conversation Monica mentioned that the stability group was often going around Clem, as his participation was not always helpful.

February 27, 2004

I spoke with Tina Laramie and she said she never told Clem there was 30 days to initiate testing. She also said that it seemed that Clem didn't have a good understanding of what was going on although the compilation of the table of tests per month was a useful tool.

March 3, 2004

I met with Clem today at our regularly scheduled weekly meeting. I followed up on a number of items. I asked him if he ever prepared the information on who performed what testing prior to the closure of St. Louis. I had requested this information from Clem on Feb. 19th. Clem responded that he already gave me the information verbally. I asked him again to write it down and I used the whiteboard to demonstrate a format, as he seemed bewildered by my request. I proposed a simple format whereby he listed all the assays and checked off whether the assays were performed by QC or BA. Later on in the conversation Clem implied that the objectives keep changing and now he has to provide the information as I requested. I pointed out that it shouldn't take more than a couple of hours to put the information together especially since he claims he already gave it to me verbally. Clem responded by saying that he needed the time to "make sure it was right".

I then asked Clem to identify which assays needed to be transferred to whom, as we would need to do a "Needs Assessment" for these assays. I again told Clem he was responsible for this action item. Since I had mentioned it initially on Feb. 26th, I asked Clem if he had made progress on this. Clem said he started working on it but couldn't articulate what he had done other than he's been reading the SOPs and talking to people.

I told Clem he wasn't meeting expectations. Clem appeared frustrated and asked what the expectation was. I told Clem that someone with his position and background would be expected to get his hands around the whole Refacto transfer issue and make it flow smoothly. Clem told me he didn't have enough time and that the objectives keep changing. He said he understood his objective was to identify the assays and find someone here in Andover to test the stability samples. I explained to Clem that his responsibility went beyond that as although he found individuals to do the testing, the impact on other projects was never considered and management was not kept in the loop. Clem said he didn't have the details as no one offered the information. I told Clem that not having the details was part of the problem and that the feedback I was getting was that he speaks in a very general way and it's the lack of details that are getting us in trouble. Clem again said he didn't have the information. I asked him if he asked anyone and he said he didn't have time. I told Clem I disagreed as I thought there was ample time to ask questions about the assays and samples.

I also told Clem that in preparation for the meeting on Friday (that I set up with Mary Denton and Tina Laramee), I expected that he would have details regarding the samples scheduled for chromogenic testing in April, i.e., can they be batched? Do they use the same standard? Clem agreed to come prepared with this information.

WYETH00473

I also asked Clem to add the "Needs Assessment" task into his timeline and that he should set a target date for completion of this deadline. Clem agreed. I asked him to share that target date with me in a day or so.

April 14, 2004

At our weekly meeting today, I followed up with Clem regarding the Needs Assessment task that he had initiated. At our last meeting (March 24th) Clem told me (and showed me) that he started the Needs Assessment for the two assays. He had allowed himself 10-12 weeks for completion of this task. I told him at that time that it was too long. Clem stated that it didn't matter, as it didn't interfere with the tech transfer activities. I told him he was interpreting the "Needs Assessment" document differently than some other key individuals were interpreting it. I encouraged him to talk this through with Dawn Block but Clem became were adamant that it wasn't necessary for him to talk to Dawn.

At today's meeting I followed up on these activities. No noticeable progress was made on the Needs Assessment document. Clem claimed it would take time, as Development was not responding to his requests. I pointed out to Clem that 12 weeks to complete this was unacceptable especially since this was his primary objective. Again, he stated that it doesn't interfere with the tech transfer. So I asked him for the status of the tech transfer and he said nothing had been done. At this point I told Clem that I was considering putting him on a PIP.

Clem was on vacation from March 26th through April 7th (and called in sick on April 8th). Clem also said he didn't know that it was his task to write the tech transfer protocols as the analysts always did that. I explained that I was trying to free up the analysts to do the science and the reason I put him into this position was that I needed someone to manage the process and think through the strategy and to write the documents. Clem said he has lots of experience overseeing tech transfer but has never written the documents. Clem then began challenging me in terms of the changes I recently made in the organization, particularly relevant to his role. Clem stated that he wasn't born yesterday and that he knew I demoted (*didn't use that word*) him. I explained to Clem that I changed things but didn't *demote* him. He said he didn't understand why I did that and I must have "something up my sleeve" and/or "someone is putting me up to this". I told Clem that those statements were not true. I then explained that he was not successful in the managerial role and that there was nothing wrong with that as we all have different areas of expertise. I told Clem that I had to take him out of that role as his staff had approached me and told me they would leave if I didn't do something about their reporting structure. Clem noted that he couldn't confirm this. I then told Clem that I put him in this role as he had previously told me (when I asked him) that tech transfer was a strongpoint for him. I explained that I was hoping he could excel in this position but to date there was insufficient productivity and not enough initiative. I also pointed out that there is a general

perception that Clem is not performing well in this role. Clem stated that he had no control of the perception of others but before I came everyone thought he was doing a good job. I told Clem that it wasn't true and that he should talk to people. He asked who? I suggested Sharleen Miele and David Holmes. Clem stated that he didn't report to these people and according to his previous manager he was doing well. I pointed out that his previous manager was not closely tied in to his daily activities and that our role in AS&T was to support the routine testing labs. I also pointed out that I had been giving Clem this feedback for almost a year now. Clem became more argumentative and I told Clem that we were obviously in disagreement and arguing the issues was not productive. The meeting ended. Shortly after the meeting, I received a note from Robyn regarding the status of Clem's monthly report (for March 2004). Clem told Robyn that he had no highlights for the month of March.

April 16th

I asked Clem about his March monthly report and he told me that since he responded as he did because of my statement (months earlier) that I didn't want everything that people were working on in their monthly reports but I wanted highlights (meaning milestones/project completions/etc). I told Clem that I knew he initiated some things such as the Needs Assessment and the timeline for the transfer of the two assays and that he should give these to me in writing as part of a monthly report. Clem did so but also included some tasks accomplished by Isabelle, Norma and Latosha (who no longer report to him).

April 22, 2004

I met with Clem today and delivered a Performance Improvement Plan (PIP) to him. Clem seemed shocked and angry. I explained to Clem that this was an issue of his performance only. I summarized the objective of the PIP and explained the three possible outcomes. I told Clem that the PIP was written such that there were two major areas that needed improvement; quality and timeliness of work and initiative. I told him I had provided some examples within the document. I then read the expectations to Clem with the due dates. Clem was argumentative about the need for the first objective (talking to Dawn Block about AQ401). Again I explained that the document was unclear as people (particularly he and Dawn, the two major stakeholders), were interpreting the document differently. Clem snickered at the due date of the second objective. My presumption (based on previous conversations with Clem) is that he thought it was too aggressive. I explained to Clem that someone at his level should be able to easily accomplish these objectives. Clem stated he would need to read the PIP, get appropriate consultation and consider his options. I responded that he was entitled to do what was necessary. I also explained to Clem that his signature would not indicate his agreement with the PIP but that I had explained the expectations. I also suggested to Clem that if he wanted to speak to HR he

WYETH00475

had the option to speaking to any of the HR reps. I told him I had talked with Chris Pajak regarding the PIP. Clem then asked if there was anything else. I responded by asking if he had any questions. Clem said, "No, he had to explore his options." The meeting ended by 4:15 (it started at 4:00). Clem went to his office, closed the door and it was still closed when I left for the day (about 5:20).

April 23, 2004

Clem called in and left a voicemail that said he was taking a personal day.

April 26, 2004

Clem arrived at work at 9:30 this morning. He did not attend the Sr. Staff meeting that was held at 11:00. Pius told me that Clem informed him he would be in training from 10-12.

I emailed Clem and asked him when he would be making a decision regarding signing the document. Clem responded by email that he was getting consultation regarding what was best for him and would let me know on Wednesday.

April 27, 2004

Clem emailed me to let me know that he needed to leave at 4:00 for an appointment.

April 29, 2004

Clem and I had our first follow up meeting for the PIP. Clem stated that although he met with Dawn and had summarized the meeting in writing (he gave me a copy), he couldn't get her to agree on the changes to AQ401. I explained to Clem that we needed to either compromise or come to some sort of agreement, as it was inappropriate to have an SOP that could be interpreted so differently. I explained that if conducting the assessment was optional (Clem's point of view), then the document should clearly state that. I also offered some other suggestions for resolving the issue. One of my suggestions was to tie the needs assessment write-up in with the transfer protocol. Clem had suggested a checklist. I agreed that would work too. In any case, I made it clear to Clem that the issue requires resolution and it was the expectation that he would resolve this issue. Clem said he understood and already had another meeting scheduled with Dawn.

Clem also told me he was working on the "Needs assessment" and would need Robyn's assistance. I told him he should ask Robyn for any assistance she could provide to him. Clem also told me he was working on the Tech transfer

document. However, Clem did not show me any documentation/draft of the "Needs Assessment" or the "Tech Transfer Qualification Protocol".

I asked Clem if he logged his activities as specified in his objectives. Clem said he did not do this, as he didn't know what I wanted. I explained again that I needed to assess how he was spending his time during the day and that he didn't need to log every minute of his time but if he spent half an hour tracking down information from an email request, he should record that. On the other hand, logging a 30 second phone call was not necessary. I asked Clem to consider the purpose of the assignment and to provide the necessary information.

I asked Clem if he had any questions and he said "no". I asked if he understood the expectations and he appeared confused (based on facial expression). I then reiterated the expectations as outlined in the PIP. Clem said he understood and the meeting ended.

May 6, 2004

Clem and I met for our second follow-up meeting to discuss the PIP. Clem provided me with a written summary of his meeting with Dawn. Although the most recent issue was resolved (i.e., validation vs. tech transfer), the original issues that I asked Clem to resolve with Dawn were not addressed in the summary. Upon questioning Clem, it first appeared as though he didn't understand what I was talking about. However, he then said the issues were being resolved in the new draft. The final line of the summary meeting as drafted by Clem stated that Dawn was initiating the changes and would provide them to Clem for concurrence. I told Clem that I was dissatisfied with that decision, as I have discussed with him, a number of times, of the need to take initiative and to delegate less. Clem became argumentative and told me that Dawn already had the revision in progress. When I asked Clem for clarification of the revision that Dawn was making, he responded "the things we just talked about." It seemed like we were going in circles so I suggested to Clem that I might discuss it further with Dawn. Clem said that was no problem.

I then asked Clem for the "Needs Assessment". Clem provided me with the draft. I thanked Clem and told him I would review it. Clem then got up and began to leave the room. I said, "wait a minute, we're not done". I then asked Clem if he updated the Refacto ATF team as they met on Tuesday, May 4th. Clem said he did not do this.

I then asked Clem for the logbook. He said that as he mentioned to me previously he was doing this unofficially. I then reminded Clem that I clarified it to him last week. I re-read the PIP objective to him. Clem said he has never had to do that and didn't think it was appropriate. I explained that I needed that

WYETH00477

*Denny's
Notes*

information so that I could evaluate how he is spending his time and how I could help him with his performance. Clem stared at me for a while and I asked him to respond. Clem said, "You've already got my response". I said, "ok". Clem got up and left the meeting.

May 12, 2004

I invited Clem to a meeting with myself, Dan Eustace, John Novak (R&D) and Anh Pham-Baginski regarding the need to transfer an ELISA from the R&D group to QC. Clem was assigned to do the Needs Assessment and to provide SOPs (for information only) to both Anh and John. Clem agreed to take on the responsibility.

I also emailed Clem today and asked him to list the changes that Dawn will be making to AQ401. I told him we would discuss those changes at our next meeting (scheduled for May 13, 2004). There was no response from Clem.

May 13, 2004

We had our third follow-up meeting to the PIP today (10:00 to 10:30). Clem read from some handwritten notes that Dawn was making two changes to the SOP AQ401. He articulated two changes that Dawn was making to the document. I asked Clem as to the timeframe for the changes and Clem said June. I asked Clem why so long and he said she was busy. I then asked Clem again why he couldn't initiate the changes. Clem shrugged his shoulders and I asked him to follow up with Dawn with the offer to update the document sooner. I explained to Clem again that we needed to be more proactive in getting things done. Clem agreed.

I then went over the edits I made to the "Needs Assessment" document that Clem gave me last week. I went through the edits line by line and Clem listened and thanked me at the end of the discussion. The edits were suggested to correct spelling, to make complete or grammatically correct sentences, for consistent terminology and to make the text less vague. For instance, in the "Purpose" section, Clem initially neglected to include both assays that were being addressed by the document. I asked Clem to make the edits and he said he had already submitted it to QRM and would make the edits now that the document was "in green".

Clem then provided me with drafts of two protocols for the Tech Transfer of the two assays. I thanked him and told him I would review the documents by next week.

I then re-iterated the new objective (assigned yesterday) about completing the "Needs Assessment" for the ProFIX ELISA. Clem stated that he already forwarded copies of the SOPs to Anh. I thanked Clem for doing that. I then

asked for an estimate of when the "Needs Assessment" would be completed. Clem said he wouldn't be able to tell me that for a couple of weeks. I asked why and Clem said he first needed to read the documents. I pointed out that it didn't take that long to read a couple of SOPs and Clem stated that he might have to dig up other information and wouldn't know for a couple of weeks.

I then asked Clem about recording his activities in a logbook. He said he didn't do this and saw no need for it as he was doing what I asked him to do. I told him I didn't know how he was spending his days and the log would help me. Clem stated that he wasn't doing anything other than what I was telling him to do. He shook his head from side to side and I asked him how he would be spending the rest of the day. Clem told me he needed to talk to the statisticians regarding the tech transfer qualification protocols that he had given me and might have to find more information. Again, I reiterated the usefulness of the log but Clem refused to consider it. The meeting ended.

May 20, 2004

I started our meeting by asking Clem if he followed up with Dawn as we discussed at the May 13th meeting. Clem responded that he did not do this, as he doesn't remember the conversation. He said he recalled that I wanted to talk to Dawn. I clarified the expectation that I expected Clem to speak directly with Dawn and to take the initiative in revising the document. I also reminded him that we needed to remove the phrase QC to QC (within same site). Clem seemed surprised that the phrase was still in the document but agreed to address it.

I then asked Clem if he made the revisions to the Needs Assessment based on the feedback I gave him at our previous meeting. Clem seemed confused but then said that the changes were already in QRM.

I provided Clem feedback on the two tech transfer protocols he drafted and provided to me the previous week (May 13th). I told Clem I was disappointed in that I expected he would do a better job on these documents. I went through my concerns line by line. My comments were widespread and addressed spelling and grammar errors, information that was scientifically invalid (in a number of cases, Clem cut and pasted from another document and it made no sense for the method he was writing about), references were incomplete and inaccurate, information was lacking and in conflict with his findings of the Needs Assessment. Clem told me this is what happens with tight deadlines. I again told Clem I believed there was ample time to get good drafts of these documents. Clem then said he already spotted some of these errors and had a newer version. I asked if he had copies of the newer versions and he said not with him. I asked him where they were and he said on his computer. I asked Clem for hard copies of these new versions and I specifically asked that he print them out right

after this meeting. Clem hesitated a little and then said ok. But I did not receive these copies to date (5/24/04).

I then asked Clem about updating the Refacto ATF team regarding the tech transfers of the assays. Clem said he has not yet done this.

I then asked Clem about recording his daily activities in a log. Clem looked surprised that I asked for this again and said that he didn't do it.

I then asked Clem about progress on the Needs Assessment for the Pro FIX ELISA that needed to be transferred to QC from Research. Clem said he's been spending lots of time reviewing documents. When I asked specifically what he was reviewing, Clem was vague and was able to name 1 or 2 documents. He then said he gave the procedure to Dan Eustace to review and was waiting for Dan's response (Dan is the ELISA SME for AS&T). I asked Clem if he knew when Dan would give him a response and Clem said "no". I asked Clem if he asked Dan about when he would be able to give Clem a response and Clem said "no". I then suggested that Clem talk to Dan and get the timeframe or let Dan know the timeframe. Clem thought he would need about 3 weeks to complete the Needs Assessment for this assay and told me he would give me a "good draft".

I told Clem I was not comfortable taking him off of the PIP as he did not meet many of his objectives. I told Clem I would consult with HR and senior management and then get back to him.

The meeting ended.

May 24, 2004

Clem called in sick. Since I will be out of town the rest of the week I left Clem an email articulating that I would speak to him about the status of the PIP when I returned. I also reminded him of the various projects he should be working on during the next week.

May 27, 2004

Clem provided the two new drafts of the tech transfer protocols to Robyn for my review. The drafts were supposedly on his computer and I had asked him to give them to me immediately following our meeting on 5/20/04. However, Clem provided them on 5/27/04. Robyn immediately faxed them to me (I was at a Wyeth meeting in Montreal).

June 1, 2004

I reviewed the new versions of the tech transfer protocols that Clem had revised and faxed to me. I was disappointed in that many of the comments I made were not addressed, spelling errors were not all corrected, the transfer strategy was not defined, and details and justification of acceptance criteria remained unclear.

June 2, 2004

Clem and I met (at 1:00) to discuss the status of the performance plan as well as the status of the work he's done on the projects since our last meeting. Chris Pajak (HR employee relations) sat in on the meeting as an observer. Chris pointed this out to Clem at the beginning of the meeting. I had also sent Clem an email earlier in the day to let him know that Chris would be joining us for the meeting, as I didn't want him to be surprised.

I proceeded with the meeting by following up on the various issues that were outstanding for Clem's performance plan. I used the email I sent to Clem (5/24/04) as my frame of reference. I started with AQ401. Clem responded that although he didn't talk to Dawn he did initiate a revision to the document. When I questioned Clem further as to what he actually did, he pointed out that he filled out the DIRF (document initiation/rejection from) and that he started revising the document. I asked to see the redlined version Clem was working on and Clem stated that he just started. Again, I asked to see it. Clem pushed a folder over to me. I looked through the document and noted only two comments that Clem had added to the document. Clem then stated that he needed to make a form and answer the trainer questions. I asked about the timeframe for getting this done and Clem stated that he couldn't tell me and hadn't thought about it. I pressed him to estimate the timing but he said he couldn't as I was asking him to do many things. I suggested we go through the rest of the issues and then assess the number of things (and their level of required effort) before discussing the timelines further. At this point I mentioned that if Clem would keep a log of his daily activities, it would assist me in understanding his claims of being too busy. Clem stated (as he has numerous other times) that he would not fulfill my request, as we don't ask everyone to do that. Chris interjected at this point that although it's true we don't request this of our employees in general, it was a reasonable request as his supervisor had concerns about his productivity. Clem began arguing with Chris. Chris pointed out that Clem's refusal to comply was "insubordination". Clem did not respond.

I then asked Clem about the status of the Needs Assessment for the two Refacto Assays. Clem told me that Bob Kitchen (Development) had reviewed the document and it was now with John Sullivan. Clem had not asked John for an estimated timeframe to review the document but agreed to follow up with John. I mentioned to Clem that I heard he had updated the Refacto ATF regarding

transfer of the Refacto assays and that it went well. I also brought up that I heard John Sullivan mentioned he did not have a qualified UV-vis spec. I asked Clem why it wasn't mentioned in the Needs Assessment and Clem responded that John had a new spec but in the meantime he could use the spec in the QC AS&T lab. I pointed out that if we are facilitating a transfer to the QC DP (drug product) lab and they didn't have the appropriate instrumentation it should be mentioned in the Needs Assessment document. Clem disagreed and said they could use ours, as we are part of QC. I agreed it was ok but I suggested the location of the qualified spec that would be used to transfer the assay be clearly identified in the Needs Assessment. Clem nodded in the affirmative. I then acknowledged that it was good that Clem updated the Refacto ATF regarding the tech transfers as it gave Clem visibility, it looked good for AS&T and was in the spirit of collaboration. I asked Clem to update the Refacto AFT on a regular basis. I suggested every 4-6 weeks (or 2-3 meetings as the team meets every two weeks).

I then asked Clem about the status of the Needs Assessment for the ProFIX ELISA. The last I heard is that he was waiting for comments from Dan. Clem said he received the feedback from Dan but hadn't started working on this document yet as he was busy with the other assignments I gave him. I asked him when he thought he could get a draft of the Needs Assessment for the ProFIX ELISA but Clem wouldn't provide an estimated date.

I then proceeded to discuss my most recent review of Clem's tech transfer documents for the two Refacto AF assays. I went through the document (starting with the A_{280} assay) page by page. I first pointed out that the transfer strategy was not defined. Clem seemed confused by my comment even though it was redlined on the first version I returned to him and even though we talked about it at length at our previous meeting. I explained to Clem that I was under the assumption that since the method was neither qualified nor validated (as documented in the Needs Assessment that was written by Clem), we couldn't transfer it in without doing a co-validation. Since I wasn't clear as to the policy and couldn't find the policy documented clearly in our SOPs, I asked two individuals who I thought were subject matter experts, David Holmes, Director of QC Labs and Lindsey Roberts, Manager of QC Contract Relations. Both responded similarly and I showed Clem David's response (provided to me by email). The response was that our practice was not to transfer methods to QC from development unless they are qualified and/or validated. Clem disagreed and said it wasn't written anywhere. I agreed that I couldn't find it documented anywhere either but it didn't take long for me to seek out our current practice and I expected that in the future Clem would take the initiative to learn our practices so that we can be consistent. Clem disagreed and said since it wasn't written down he could do it the way he wanted. I disagreed and said that the SOP probably should be revised and we shouldn't proceed knowing it's not the right thing to do. I don't recall any resolution to this disagreement although Clem did point out that his Needs Assessment was inaccurate (Bob gave him more info

upon reviewing the document) in that a validation report did exist. Nevertheless, I encouraged Clem to speak directly with David and/or Lindsey. I also pointed out to Clem that during my search for this information I came across SOP #AD180. AD180 identifies a process for transferring methods that includes the formation of a Tech Transfer Oversight Committee, a Project Team Leader and a number of other requirements. I told Clem I was concerned we were not in compliance. Clem said he was familiar with the document but his explanation as to whether or not we were following it was vague and unclear to me. I told Clem that I had requested a copy of the official signatory page from QRM and that once I received the information I would forward him a copy. I asked Clem to discuss the issues in AD180 with the experts to identify where we might be deficient in our processes to transfer the methods from Development to QC. Clem agreed. We then got back to my edits on the two documents. I pointed out numerous areas where more information was required as the text was unclear regarding details such as identification of controls and standards that needed to be transferred to QC, acceptance criteria (I suggested a table to make things more clear), an explanation as to why we were doing precision experiments, spelling errors (pointed out previously but still uncorrected), and overall clarity to the text. I told Clem I would provide him with my comments after I made a copy of them. I provided the comments to Clem at the end of the day.

The most disturbing aspect of the meeting for me was Clem's insistence (throughout the meeting) that I was out to get him from the day I started working at Wyeth. He pointed out an incident with Andy (one of Pius's reports). Clem said that I called him (Clem) into my office and scolded him for his management style. I explained to Clem that I spoke to him (as opposed as directly to Pius or Andy) since Pius reported to Clem and I thought it was the respectful thing to do. I told Clem I recalled that I told him he needed to talk to Pius as Andy didn't seem to have enough to do and was spending too much time on the web. (*As I recall, but this was not discussed today, I followed up with Clem and Pius and was told at the time that Andy was not a very good performer. I asked them what rating he received on his last performance appraisal and was told a "4". I asked why and I was told that expectations for him were very low and he exceeded those expectations. I do recall telling both Clem and Pius that it was an inappropriate reason to give an employee a 4.*)

Clem then began stating that he (Clem) did a good job prior to my joining Wyeth and got good reviews, etc. Chris interjected that this was an inaccurate statement in that he reviewed Clem's performance appraisals from Pearl River and the received ratings and feedback were similar to what I had provided Clem. Clem then began to talk about his "inner strength and what keeps him going." Clem began quoting what seemed to be religious scripture. Although I didn't understand a lot of what he was reciting I did hear him say something like "thou who condemns, will themselves be condemned". I considered this a personal threat and had difficulty listening to the rest of the religious verse but at times heard him mention God, his maker and judgment. Finally, I interjected and said

"Clem, what does this have to do with your performance? I don't know what you are talking about." Clem then said something about my plans and intentions. Both Chris and I asked for clarification but Clem kept talking without making a lot of sense. Clem made a statement that suggested he thought I was setting him up. Chris interjected and said that his role as an HR rep is to make sure managers treat employees fairly, do not make unreasonable requests of employees and do not "set employees up for failure". Chris reminded Clem that he was available if Clem wanted to speak to him and that he wasn't part of the management team. Chris also told Clem that if Clem was not comfortable talking to him, he could seek out any of the other HR reps. Chris mentioned Tonia, Gillian and Pia as examples. Clem thanked Chris for the information. The conversation then deteriorated again and finally Clem said to me, "you have your plans and I have mine". In view of his previous comments regarding condemnation, I again felt threatened.

The last item we discussed was the PIP extension. Chris mentioned that he and I had discussed this previous to this meeting and had agreed upon a 3-week extension of the PIP beyond the original end date. The new end date of the PIP is June 17, 2004. I initialed the change to the PIP but Clem declined to initial the document. Chris then initialed the document.

Prior to concluding the meeting we reviewed the outstanding items and I reminded Clem that I expected an estimate of date of completion of the following items by tomorrow (June 3, 2004). I suggested that Clem take notes, as he hadn't written anything down throughout the entire meeting.

- answer trainer questions pertaining to revisions of SOP AQ401.
- design a form to replace the Needs Assessment report
- completion of draft of Needs Assessment for FIX ELISA transfer
- review validation report for A₂₈₀ assay for Refacto AF (depending on its completeness the Needs Assessment and/or Tech Transfer protocol may need to be revised)
- revise the two tech transfer documents for Refacto AF based on feedback provided today

I also reminded Clem that he speak to the signatories of AD180 to identify any areas of the tech transfer process with which we may not be currently in our compliance.

The meeting ended at 2:00.